

V. GRANTEE RESPONSIBILITIES FOR INVENTION REPORTING

Inventions Must Be Reported

The Bayh-Dole Act (Public Law 96-517) of 1980 requires that inventions made with Federal funds be reported. This regulation was promulgated by the Department of Commerce and is applicable to all agencies. It applies to all funding agreements, which include contracts, grants, and cooperative agreements. It does not apply to cooperative research and development agreements (CRADAs).

The Bayh-Dole Act

The Bayh-Dole Act encourages researchers to patent and market their inventions by guaranteeing patent rights. It automatically grants first rights to a patent for an invention fully or partially funded by a Federal agency to the university or grantee/contractor institution. To obtain these benefits, however, the inventor and the institution must satisfy several reporting requirements that protect the rights of the Government.

This landmark legislation is important because it gives nonprofit organizations and small business firms the right to retain title to inventions. Its objective is to use the patent system to promote the use of inventions arising from federally supported research, encourage participation of small business firms in federally supported research and development, promote collaboration between commercial and nonprofit organizations, ensure that inventions made by nonprofit organizations and small business firms are used in a manner that promotes free competition and enterprise, promote commercialization and public availability of inventions made in the U.S. by U.S. industry and labor, and ensure that the Government obtains sufficient rights to prevent the unreasonable use of inventions.

Definition of an Invention

“Any invention or discovery which is or **may be** patentable or otherwise protectable under title 35 or any novel variety of plant which is or may be protected under the plant variety protection act (7 USC 2321 et seq.)”

According to this definition from the U.S. Code, it is clear that an invention need not be patentable to be reported to NIH, and it may not be known whether it is patentable until a patent application has been filed and prosecuted.

Inventions That Must Be Reported

A reportable invention or “Subject Invention” as defined in the Bayh-Dole Act is any invention conceived or first actually reduced to practice with funds from an NIH grant. An invention could still be reportable even after an initial patent application has been filed. The fact that you may have filed a patent application prior to applying for an NIH grant does not mean it is not reportable particularly if the invention is first actually reduced to practice in the performance of work on the grant. If you are unsure whether the discovery is a subject invention and if you are concerned that the invention is particularly valuable, you may wish to obtain an opinion from an outside patent counsel.

Rights of Grantees for Inventions Made With NIH Funds

SBIR grantees may retain title to subject inventions throughout the world provided the government is granted a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention. A license to the U.S. Government form is illustrated on page 49. Occasionally a firm will argue that it does not want to accept a grant if its inventions will be subject to a license to the Government. **Nonetheless, under 28 USC 1498, all U.S. patents are subject to a license to the Government, although reasonable compensation must be provided.**

Invention Reporting Process

The awardee organization is responsible for the following:

- Disclosing an invention to the NIH in writing within two months of the inventor's initial report to the organization. This disclosure must be complete in technical detail to convey a clear understanding of the invention.
- Electing title to the invention within two years of disclosure to NIH. Sometimes election is made at the time of disclosure of the invention when it is clear that a grantee plans to file a patent application. **For inventions that have been disclosed to the public, notify NIH sixty days prior to the statutory bar date, which is usually one year after the date of publication, sale, or public use.**
- Informing NIH when it does not wish to take title to an invention.
- Filing a patent application within one year of election of title or publication, whichever is earlier. The patent application must include the Federal support statement: “This invention was made with U.S. Government support under (grant or contract number) awarded by (agency). The U.S. Government has certain rights in the invention.” The page of the patent application that contains the Federal support clause must be sent to NIH.

- Providing NIH with a nonexclusive, nontransferable, irrevocable paid-up license to make or use the invention throughout the world.
- Providing NIH with the patent number and issue date.
- Reporting use every year subsequent to filing a patent.
- Completing a final invention statement prior to closeout of the NIH grant or contract. This form (HHS 568) is to be submitted directly to the awarding NIH Institute or Center (IC).

Unless otherwise specified (as with Form HHS 568) all this information should be sent to Extramural Invention Reporting, National Institutes of Health, 6701 Rockledge Drive, Room 3188, Bethesda, MD 20892.

NIH has a new electronic system for reporting inventions on the Internet, called Edison (Extramural Invention Information Management System). You can log in at <http://era.info.nih.gov/edison/>.

See **Table 7** for a summary of required actions and when they are due.

Consequences of Failing to Comply

Failure to report inventions appropriately is usually caused by a misunderstanding of the legislation and its implementing regulations or the incorrect premise that the Government will inappropriately interfere with the commercialization of subject inventions.

In fact, the Bayh-Dole Act provides very few restrictions on commercial development. As long as Government-funded inventions are reported and commercially viable inventions are being reasonably developed by the organization (which is in everyone's interest), Government involvement is limited to retaining its confirmatory, nonexclusive license.

On the other hand, failure to comply with the reporting requirements of the Standard Patent Rights Clause [37 CFR 401.14(d)] can result in loss of the recipient's rights to an invention or the use of the Government's right to march-in. In addition, the latest version of the PHS Form 398 grant application (revised 1995) includes a penalty clause for the improper reporting of an invention or failure to report an invention.

Table 7. Action and Timing of Invention Reporting Requirements

ACTION	WHEN
Employee Agreement to Disclose All Inventions: Requires written agreement with all employees, except clerical and nontechnical, to promptly disclose inventions. Institution must identify grantee institution personnel to whom disclosures must be made.	Upon acceptance of NIH funding.
Invention Disclosure: Must be complete in technical detail and given in writing to NIH. Disclosure also identifies inventor(s), NIH grant or contract number(s), any date of public disclosure.	Within two months of inventor's initial report to the institution.
Election of Title to Invention: Must be given in writing to NIH.	Within two years of disclosure to NIH. For inventions disclosed to the public, notify NIH sixty days prior to the statutory bar date, which is usually one year after the date of publication, on sale, or public use. Publications include abstracts and posters.
Nonelection of Title to Invention: Must be given to NIH in writing along with available information on whether the inventor(s) would like to obtain title.	For inventions not disclosed to the public, notify NIH sixty days prior to the end of the two-year disclosure period .
Patent Application: Provide NIH with 1) confirmatory license to the government and 2) page of the patent application that contains the Federal support clause, "This invention was made with government support under (grant or contract number) awarded by (agency). The government has certain rights in the invention." Upon request, provide the entire patent application.	Within one year of election of title or publication, whichever is earlier.

ACTION	WHEN
Issued Patent: Provide NIH with patent number and issue date.	At time of issuance of patent.
Request for Extension of Time: For disclosure, election, or filing.	Prior to deadline for disclosure, election of title, or patent filing unless good cause is shown for a later request.
Discontinuation of Patent Application, Payment of Maintenance Fees, or Defense in a Reexamination or Opposition Proceeding on a Patent: Notify NIH and provide relevant information and documents, e.g., patent application or patent, such that a determination to protect government interests can be made.	Not less than thirty days of the response period required by the relevant patent office.
Annual Utilization Report: Required for all inventions where patent applications have been filed or where it has been licensed as a biological material but not patented. Includes status of development, date of first commercial sale or use, and gross royalties.	Every year subsequent to filing a patent application or licensing as a biological material.
Final Invention Statement and Certification (Form HHS 568): List all inventions made under the grant or indicate that there were none.	Within ninety days following termination of the grant.

FOR FURTHER INFORMATION:

Division of Extramural Invention and
Technology Resources
National Institutes of Health
6701 Rockledge Drive MSC 7750
Bethesda, MD 20892-7750
Tel: (301) 435-1986
Fax: (301) 480-0272

Counsel on Intellectual Property
Office of the General Counsel
National Institutes of Health
Building 31, Room 2B-50
Bethesda, MD 20892
Tel: (301) 496-4108
Fax: (301) 402-1034

License to the United States Government

Invention Title:_____

Inventor(s):_____

Patent or Application Serial No._____

U.S. Filing/Issue Date:_____

Grant/Contract Identification Number(s):_____

Foreign Applications filed/intended in (countries):_____

The invention identified above is a Subject Invention under **35 U.S.C. 200, et seq.**, and the Standard Patent Rights clause at **37 CFR 401.14 or FAR 52.227-11**, which are included among the terms of the above-identified grant/contract award from the Public Health Service/National Institutes of Health. This document is confirmatory of:

- I. The nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the invention described in any patent application and in any and all divisions, continuations, and continuations in part, and in any and all patents and re-issues granted thereon throughout the world; and
- II. All other rights acquired by the Government by reason of the above identified grant/contract award and the laws and regulations which are applicable to the award.

The Government is hereby granted an irrevocable power to inspect and make copies of the above-identified patent application.

Signed this _____ day of _____ 19_____

By _____
(Grantee/Contractor Official and Title)

For _____
(Organization)

At _____
(Business Address)

VI. MODEL AGREEMENTS

NIH STTR Model Agreement

ALLOCATION OF RIGHTS IN INTELLECTUAL PROPERTY AND RIGHTS TO CARRY OUT FOLLOW-ON RESEARCH, DEVELOPMENT, OR COMMERCIALIZATION

Annotation by Joyce Brinton

Director, Harvard University Office for Technology and Trademark Licensing

This Agreement between _____, a small business concern (“SBC”) organized as a _____ under the laws of _____ and having a principal place of business at _____, and _____, a research institution (“RI”) having a principal place of business at _____ is entered into for the purpose of allocating between the parties certain rights relating to an STTR project to be carried out by SBC and RI (hereinafter referred to as the “PARTIES”) under an STTR funding agreement that may be awarded by the National Institutes of Health (NIH) to SBC to fund a proposal entitled: “_____” submitted, or to be submitted, to the NIH by SBC on or about _____.

1. Applicability of this Agreement.

- A. This Agreement shall be applicable only to matters relating to the STTR project referred to in the preamble above.
- B. If a funding agreement for an STTR project is awarded to SBC based upon the STTR proposal referred to in the preamble above, SBC will promptly provide a copy of such funding agreement to RI, and SBC will make a subaward to RI in accordance with the funding agreement, the proposal, and this Agreement. If the terms of such funding agreement appear to be inconsistent with the provisions of this Agreement, the parties will attempt in good faith to resolve any such inconsistencies. However, if such resolution is not achieved within a reasonable period, SBC shall not be obligated to award nor RI to accept the subaward, as the case may be. If a subaward is made by SBC and accepted by RI, this Agreement shall not be applicable to contradict the terms of such subaward or of the funding agreement awarded by the NIH to SBC except on

the grounds of fraud, misrepresentation, or mistake, but shall be considered to resolve ambiguities in the terms of the subaward.

The above provides both SBC and RI the right to withdraw from participation in the STTR project if they are unable to resolve differences between the terms of the funding agreement, the proposal, and this Agreement

- C. The provisions of this Agreement shall apply to any and all consultants, subcontractors, independent contractors, or other individuals employed by SBC or RI for the purposes of this STTR project.

The above means that SBC and RI must pass down the terms of this Agreement to their consultants and subcontractors, etc.

2. Background Intellectual Property.

It is possible that one or both Parties may possess rights in background intellectual property, that is intellectual property not otherwise subject to this Agreement, which would be useful or essential to the practice or commercialization of the results of this Agreement. For example, the RI might own a patent which would be infringed by the SBC when it attempted to commercialize the results of this Agreement unless a license was obtained from the RI. Where the Parties determine that background technology may exist, consideration should be given to negotiating license rights which will allow the practice and commercialization of the results of this Agreement.

This is usually accomplished by RI granting SBC an option to obtain license rights to the Background Intellectual Property if that is required to commercialize the results of the STTR project – see sample Harvard STTR agreement.

3. Project Intellectual Property.

- A. “Project intellectual property” means the legal rights relating to inventions (including Subject Inventions as defined in 37 CFR 401), patent applications, patents, copyrights, trademarks, mask works, trade secrets, and any other legally protectable information, including computer software, first made or generated during the performance of this STTR Agreement.

Some RI will delete trade secrets from this list since many RIs do not agree to keep the results of their research confidential and thus cannot provide trade secret protection for the results of the STTR project. Nonetheless, there may be unpublished results to which the SBC could be granted rights, but the RI might be unable to guarantee that those results would remain unpublished.

- B. The rights of the Parties to subject inventions made by their employees in the performance of this STTR Agreement shall be as set forth in the Patent rights clause of 37 CFR 401.14. The NIH may obtain title to any subject invention not elected by a party as set forth in the Patent rights clause.

Unless otherwise agreed in writing, project intellectual property shall be owned by the party whose employees make or generate the project intellectual property. Jointly made or generated project intellectual property shall be jointly owned by the Parties unless otherwise agreed in writing. The SBC shall have the first option to perfect the rights in jointly made or generated project intellectual property unless otherwise agreed in writing.

In addition to the Government's rights under the Patent rights clause of 37 CFR 401.14, the Parties agree that the Government shall have an irrevocable, royalty free, nonexclusive license for any Government purpose in any project intellectual property.

1. Any revenues and profits resulting from the practice, licensing, or exploitation of project intellectual property shall be allocated between the SBC and the RI as follows:

	SBC Percent	RI Percent
Revenues		
Profits		

Most RIs will require that this clause be changed since sharing in “profits” might jeopardize the RI’s tax-exempt status. A typical solution is to deal with this in terms of a royalty to be paid by SBC to RI if SBC is granted license rights to project intellectual property. See sample Harvard STTR agreement.

2. Expenses and other liabilities associated with the development and marketing of any product, process, or other innovation or invention shall be allocated as follows: the SBC will be responsible for _____ percent and the RI will be responsible for _____ percent.

This is usually not appropriate for RIs – it is anticipated that if the SBC decides to proceed with commercialization of the results of the STTR project and receives a license from RI for any RI project intellectual property, then SBC will undertake the development and marketing of any resulting products. It might do so with its own resources or with further support from the Federal Government under SBIR grants or with resources obtained from

other commercial entities through a joint venture or R&D partnership, etc. See sample Harvard agreement.

- C. The Parties agree to disclose to each other, in writing, each and every Subject Invention, which may be patentable or otherwise protectable under the United States patent laws in Title 35, United States Code. The Parties acknowledge that they will disclose Subject Inventions to each other within _____ months after their respective inventor(s) first disclose the invention in writing to the person(s) responsible for patent matters of the disclosing Party. All written disclosures of such inventions shall contain sufficient detail of the invention and identification of any statutory bars and shall be marked confidential in accordance with 35 U.S.C. Section 205. Disclosures to the NIH shall be within the time provided in paragraph (c)(1) of the Patent rights clause of 37 CFR 401.14.

This clause provides the SBC and RI with a procedure for sharing information about Subject Inventions which are project intellectual property and thus permits the parties to cooperate in evaluating and protecting those inventions. It also specifies that each party will report the Subject Inventions to the government as required by law.

- D. Each party hereto may use project intellectual property of the other nonexclusively and without compensation in connection with research or development activities for this STTR project, including in STTR project reports to the NIH and proposals to the NIH for continued funding of this STTR project through additional phases.

This clause insures that SBC and RI may continue to use the project intellectual property of the other party in this and follow-on STTR projects. SBCs rights to use RI project intellectual property for other purposes are dealt with in later clauses.

- E. SBC will have an option to commercialize the project intellectual property of RI, subject to any rights of the Government therein. The following terms apply unless other provisions are negotiated:
1. Where project intellectual property of RI is a potentially patentable invention, SBC will have an exclusive option for a sole license to such invention, for an initial option period of _____ months after such invention has been reported to SBC. SBC may, at its election and subject to the patent expense reimbursement provisions of this section, extend such option for an additional _____ months by giving written notice of such election to RI prior to the expiration of the initial option period. During the period of such option following notice by SBC of election to extend, RI will pursue and maintain any patent

protection for the invention requested in writing by SBC and, except with the written consent of SBC or upon the failure of SBC to reimburse patenting expenses as required under this section, will not voluntarily discontinue the pursuit and maintenance of any United States patent protection for the invention initiated by RI or of any patent protection requested by SBC. For any invention for which SBC gives notice of its election to extend the option, SBC will, within _____ days after invoice, reimburse RI for the expenses incurred by RI prior to expiration or termination of the option period in pursuing and maintaining (i) any United States patent protection initiated by RI and (ii) any patent protection requested by SBC. SBC may terminate such option at will by giving written notice to RI, in which case further accrual of reimbursable patenting expenses hereunder, other than prior commitments not practically revocable, will cease upon RI's receipt of such notice. At any time prior to the expiration or termination of an option, SBC may exercise such option by giving written notice to RI, whereupon the Parties will promptly and in good faith enter into negotiations for a license under RI's patent rights in the invention for SBC to make, use and/or sell products and/or services that embody, or the development, manufacture and/or use of which involves employment of, the invention. The terms of such license will include: (i) payment of reasonable royalties to RI on sales of products or services which embody, or the development, manufacture or use of which involves employment of, the invention; (ii) reimbursement by SBC of expenses incurred by RI in seeking and maintaining patent protection for the invention in countries covered by the license (which reimbursement, as well as any such patent expenses incurred directly by SBC with RI's authorization, insofar as deriving from RI's interest in such invention, may be offset in full against up to _____ of accrued royalties in excess of any minimum royalties due RI); and, in the case of an exclusive license, (iii) reasonable commercialization milestones and/or minimum royalties.

The above clause is one that the parties may decide to modify depending upon the circumstances involved in the STTR project, the area of technology involved, the potential market for products which might result from the STTR project, and other factors. However, the above approach is typical of these agreements and allows detailed license terms to be negotiated when the parties know what the resulting intellectual property is and what its potential value might be.

2. Where project intellectual property of RI is other than a potentially patentable invention, SBC will have an exclusive option for a license, for an option period extending until _____ months following completion of RI's performance of that phase of this STTR project in which such project intellectual property of RI was developed by RI. SBC may exercise such option by giving written notice to RI, whereupon the parties will promptly and in good faith enter into negotiations for an appropriate license under RI's interest in the subject matter for SBC to make, use and/or sell products or services which embody, or the development, manufacture and/or use of which involve employment of, such project intellectual property of RI. The terms of such license will include: (i) payment of reasonable royalties to RI on sale of products or services that embody, or the development, manufacture or use of which involves employment of, the project intellectual property of RI and, in the case of an exclusive license, (ii) reasonable commercialization milestones and/or minimum royalties.

The comments regarding the preceding clause apply here as well.

3. Where more than one royalty might otherwise be due in respect of any unit of product or service under a license pursuant to this Agreement, the parties shall in good faith negotiate to ameliorate any effect thereof that would threaten the commercial viability of the affected products or services by providing in such license(s) for a reasonable discount or cap on total royalties due in respect of any such unit.

This clause is also one which the parties may decide to alter, depending on the likelihood of multiple royalties being required for a project to be manufactured and sold by SBC. Since most RIs are committed to seeing their inventions developed into products, they are usually quite willing to negotiate financial terms in their license agreements which ensure that the licensee company has adequate financial incentives to pursue rapid development of the technology. Thus, if royalties to third parties are likely to significantly erode the profit potential for the SBC, it's in the RI's interest to work out a solution which will avoid SBC deciding that the project is not worth the development investment.

4. Follow-on Research or Development.

All follow-on work including any licenses, contracts, subcontracts, sublicenses or arrangements of any type shall contain appropriate provisions to implement the project intellectual property rights provisions of this Agreement and insure that the Parties and the Government obtain and retain such rights granted herein in all future resulting research, development, or commercialization work.

5. Confidentiality/Publication.

- A. Background intellectual property and project intellectual property of a party, as well as other proprietary or confidential information of a party, disclosed by that party to the other in connection with this STTR project shall be received and held in confidence by the receiving party and, except with the consent of the disclosing party or as permitted under this Agreement, neither used by the receiving party nor disclosed by the receiving party to others, provided that the receiving party has notice that such information is regarded by the disclosing party as proprietary or confidential. However, these confidentiality obligations shall not apply to use or disclosure by the receiving party after such information is or becomes known to the public without breach of this provision or is or becomes known to the receiving party from a source reasonably believed to be independent of the disclosing party or is developed by or for the receiving party independently of its disclosure by the disclosing party.

Some RIs may prefer to delete the above clause and to agree that no confidential information will be exchanged between the parties or to have such arrangements handled as personal commitments by the scientists involved. While this may appear to be a problem for the SBC, it is generally manageable through the negotiation of contract language to address the concerns of both the SBC and the RI.

- B. Subject to the terms of paragraph (A) above, either party may publish its results from this STTR project. However, the publishing party shall provide the other party a thirty-day period in which to review proposed publications, identify proprietary or confidential information, and submit comments. The publishing party shall not publish or otherwise disclose proprietary or confidential information identified by the other party, and the publishing party will give full consideration to all comments before publication. Furthermore, upon request of the reviewing party, publication will be deferred for up to _____ additional days for preparation and filing of a patent application which the reviewing party has the right to file or to have filed at its request by the publishing party.

Depending upon the RI's policy regarding publication and confidential information, this clause (as well as the preceding clause) may require negotiation. However, all RIs recognize the importance of reviewing publications to identify inventions and protect them by filing patent applications. It is clearly in the interest of both RI and SBC to find ways to ensure that Subject Inventions are identified and protected before publication.

6. Liability.

- A. Each party disclaims all warranties running to the other or through the other to third parties, whether expressed or implied, including without limitation warranties of merchantability, fitness for a particular purpose, and freedom from infringement, as to any information, result, design, prototype, product, or

process deriving directly or indirectly and in whole or part from such party in connection with this STTR project.

- B. SBC will indemnify and hold harmless RI with regard to any claims arising in connection with commercialization of the results of this STTR project by or under the authority of SBC. The parties will indemnify and hold harmless the Government with regard to any claims arising in connection with commercialization of the results of this STTR project.

7. Termination.

- A. This Agreement may be terminated by either Party upon _ days written notice to the other Party. This Agreement may also be terminated by either Party in the event of the failure of the other Party to comply with the terms of this Agreement.
- B. In the event of termination by either Party, each Party shall be responsible for its share of the costs incurred through the effective date of termination, as well as its share of the costs incurred after the effective date of termination, and which are related to the termination. The confidentiality, use, and/or non-disclosure obligations of this Agreement shall survive any termination of this Agreement.

AGREED TO AND ACCEPTED

Small Business Concern

By:_____ Date:_____

Print Name: _____

Title: _____

Research Institution

By:_____ Date:_____

Print Name: _____

Title: _____

Harvard Model Agreement

COLLABORATIVE RESEARCH AGREEMENT AND ALLOCATION OF RIGHTS IN INTELLECTUAL PROPERTY UNDER AN STTR RESEARCH PROGRAM

This Agreement between _____ (hereafter SBC), a small business concern organized as a _____ corporation having an address at _____ and the President and Fellows of Harvard College (hereafter Harvard), a research institution having a place of business at 124 Mt. Auburn St., Suite 410 South, Cambridge, MA 02138, is entered into for the purpose of allocating between the parties certain rights relating to an STTR project to be carried out by SBC and Harvard (hereafter referred to as the “Parties”) under an STTR funding agreement that may be awarded by NIH to SBC to fund a proposal dated _____ entitled “_____.”

Whereas, Harvard has information and/or proprietary technology relating to _____; and

Whereas, SBC has information and/or proprietary technology relating to _____; and

Whereas, the proposed research project is to jointly _____ (hereafter “RESEARCH PROGRAM”); and

Whereas, should the efforts under the RESEARCH PROGRAM be successful, it is possible that the resulting body of intellectual property might include software or potentially patentable aspects, and it is the mutual desire of the Parties that any patentable inventions and discoveries or software conceived and reduced to practice under the RESEARCH PROGRAM will be commercialized as rapidly as feasible.

Now, Therefore, in consideration of the foregoing and the mutual covenants and agreements contained herein, the Parties agree as follows:

1. Applicability of This Agreement

- A. This Agreement shall be applicable only to matters relating to the STTR project referred to in the preamble above.
- B. If a funding agreement for an STTR project is awarded to SBC based upon the STTR proposal referred to in the preamble above, SBC will promptly provide a copy of such funding agreement to Harvard, and SBC will make a subaward to Harvard in accordance with the funding agreement, the proposal, and this Agreement. If the terms of such funding agreement appear to be inconsistent

with the provisions of this agreement, the Parties will attempt in good faith to resolve any such inconsistencies. However, if such resolution is not achieved within a reasonable period, SBC shall not be obligated to award nor Harvard to accept the subaward, as the case may be. If a subaward is made by SBC and accepted by Harvard, this agreement shall not be applicable to contradict the terms of such subaward or of the funding agreement awarded by NIH to SBC except on the grounds of fraud, misrepresentation, or mistake, but shall be considered to resolve ambiguities in the terms of the subaward.

- C. The provisions of this Agreement shall apply to any and all consultants subcontractors, independent contractors, or other individuals employed by SBC or Harvard for the purposes of this STTR project.

2. Background Intellectual Property

- A. The subject matter described and claimed in U.S. Patent Application number which has previously been developed by Harvard shall be considered Harvard Background Intellectual Property.
- B. Harvard agrees to grant SBC, as part of any license granted to SBC for project intellectual property, a non-exclusive license to use the above mentioned Background Intellectual Property in connection with commercialization of the project intellectual property, to the extent that such use is reasonably necessary for practical, efficient and competitive commercialization of such project intellectual property. Such license shall be subject to any rights of the Government or other sponsors, and shall be granted upon the condition that SBC pay Harvard a royalty, consistent with fair market practices, on net sales or leases made by or under the authority of SBC of any product or service that embodies, or the manufacture or normal use of which entails the use of all or any part of such Harvard Background Intellectual Property.

3. Project Intellectual Property

- A. “Project intellectual property” means the legal rights relating to Subject Inventions as defined in 37 CFR 401, and any resulting patent applications or patents, as well as any software first conceived and reduced to practice during the performance of this STTR Agreement.
- B. The rights of the Parties to Subject Inventions made by their employees in the performance of the STTR agreement shall be as set forth in the Patent Rights clause of 37 CFR 401.14 (“Patent Rights clause”). The NIH may obtain title to any Subject Invention not elected by a Party as set forth in the Patent Rights clause.

- C. Project intellectual property shall be owned by the Party whose employees make or generate the project intellectual property. Jointly made or generated project intellectual property shall be jointly owned by the Parties, with each Party having an undivided interest therein. The SBC shall have the first option to perfect the Parties' rights in jointly made or generated project intellectual property unless agreed otherwise in writing.
- D. In addition to the Government's rights under the Patent Rights clause, the Parties agree that the Government shall have an irrevocable, royalty free, non-exclusive license for any Governmental purpose in any project intellectual property.
- E. The Parties agree to disclose to each other, in confidence and in writing, each and every Subject Invention and any software created as part of the STTR project. The Parties acknowledge that they will disclose Subject Inventions to each other and to NIH within two (2) months after their respective inventor(s) first disclose the invention in writing. Such disclosure to NIH shall be in accordance with the Patent Rights clause.
- F. Each Party hereto may use project intellectual property of the other non-exclusively and without compensation in connection with research or development activities for this STTR project, including inclusion in STTR project reports to NIH and proposals to NIH for continued funding of this STTR project through additional phases.
- G. SBC will have an option to commercialize the project intellectual property of Harvard subject to any rights of the Government or other sponsors as follows:
 - 1. SBC will have an exclusive option for an exclusive license to such project intellectual property (whether solely owned by Harvard or jointly owned by Harvard and SBC) for an option period of six (6) months after such project intellectual property has been reported to SBC. During the period of such option, Harvard will pursue and maintain any patent protection for any Subject Invention requested by SBC provided SBC agrees to reimburse Harvard for its out-of-pocket expenses. Except with the written consent of SBC, Harvard will not voluntarily discontinue the pursuit and maintenance of any US patent protection during this option period. SBC may terminate such option at will by giving written notice to Harvard and by so doing shall relinquish all rights to said project intellectual property.
 - 2. At any time prior to the expiration or termination of an option, SBC may exercise such option by giving written notice to Harvard, whereupon the Parties will promptly and in good faith enter into

negotiations for a license under Harvard's rights in the project intellectual property. The terms of such license shall be consistent with Harvard's policies and Governmental regulations and will include but not be limited to: (i) payment of reasonable royalties to Harvard on sales or leases of products or services which embody, or the development, manufacture, use, or sale of which involve employment of, the project intellectual property; (ii) reimbursement by SBC of expenses incurred by Harvard in seeking and maintaining patent protection for the project intellectual property; (iii) due diligence milestones; and (iv) insurance and indemnity provisions acceptable to Harvard's insurance carrier.

3. Where more than one royalty might otherwise be due for any product or service under a license pursuant to this Agreement, the Parties shall in good faith negotiate to ameliorate any effect thereof that would threaten the commercial viability of the affected products or services by providing in such license(s) for a reasonable discount or cap on total royalties due in respect of any such product or service.

3. Patent Prosecution and Commercialization for Jointly Owned Project Intellectual Property

- A. Although the Parties agree that each has responsibility for management of project intellectual property produced by its employees in accordance with appropriate government regulations and its own institutional policy, it is recognized that more effective enablement of commercialization of jointly owned project intellectual property will require a unified approach by the Parties. Therefore, if the STTR program is funded, the following procedural framework will be put into place for the handling of jointly owned project intellectual property.
 1. Shortly following the identification of any jointly owned project intellectual property, technical and patent representatives of each Party will discuss details of handling such jointly owned project intellectual property.
 2. One Party shall be designated the Lead Party to take primary responsibility for protection of such jointly owned project intellectual property. If patent applications are to be filed, the Lead Party will ensure that the other Party is kept informed and has an opportunity to review and comment on patent prosecution.

3. As with project intellectual property solely owned by Harvard, SBC shall have option rights as outlined above for Harvard's ownership interest in such jointly owned project intellectual property.
4. In the event that SBC decides not to exercise its option to Harvard's ownership interest, SBC and Harvard may agree to undertake a cooperative licensing effort. At that point, the Lead Party shall assume sole responsibility for identifying potential commercial licensees and for negotiating the terms of commercial license agreements. Such license agreements will require the approval of both Parties, and such approval shall not be unreasonably withheld. Any revenues generated by such license agreements after deduction of any out-of-pocket patent prosecution expenses and a sum for administrative overhead (such sum to be determined by both Parties) shall be divided equally between the Parties no less often than once per year. Each Party shall be solely responsible for calculating and distributing to its respective inventor(s) any share of net revenues payable to such inventor(s) in accordance with such Party's institutional policy.

4. **Publication and Confidentiality**

- A. Either Party may publish its results from this STTR project and each Party agrees to provide to the other a copy of any such publications at the time of submission. Whenever possible, the publishing party shall provide the other Party a thirty (30) day period in which to review proposed publications, identify material on which patent applications should be filed, and submit other comments. Each Party will give serious and good-faith consideration to any comments received from the other provided, however, that such comments are received in sufficient time so as not to delay publication.
- B. In the event that SBC desires to provide background confidential information to Harvard's investigators, it may do so under an agreement negotiated with such investigator as an individual (other than a student) concerning any such disclosures, so long as such agreements are consistent with Harvard's rights under other provisions of this Agreement and with its publication and collaboration policies. Harvard shall have no responsibility for maintaining the confidentiality of such information, nor shall Harvard require any investigator to enter into such an individual agreement. In no event shall such an individual agreement prevent the Harvard investigator from publishing the results of his/her research under this STTR project.

5. Liability

- A. Each party disclaims all warranties running to the other or through the other to third parties, whether expressed or implied, including without limitation warranties of merchantability, fitness for a particular purpose, and freedom from infringement, as to any information, result, design, prototype, product or process deriving directly or indirectly and in whole or part from such Party in connection with this STTR project.
- B. SBC will indemnify and hold harmless Harvard with regard to any claims arising in connection with commercialization of the results of this STTR project by or under the authority of SBC.

6. Governing Laws, Settling Disputes

- A. This Agreement and any to follow in this collaborative effort shall be governed by and interpreted in accordance with the laws of the State of Colorado and the Commonwealth of Massachusetts.
- B. Any controversy or any disputed claim by either of the Parties under or related to this Agreement shall be settled by arbitration, upon the request of either Party, by a single arbitrator in accordance with the Commercial Arbitration Rules of the American Arbitration Association.

7. Termination

- A. This Agreement shall remain in force for the period during which the Parties are being funded by NIH for this STTR project unless it is superseded by other written agreements among the Parties and it shall automatically terminate should either Party withdraw from the collaborative program. This Agreement may be terminated by either Party in the event of the failure of the other Party to comply with the terms of this Agreement.
- B. In the event of termination by either Party, each Party shall be responsible for its obligations through the effective date of termination.

AGREED TO AND ACCEPTED . . .